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WITNESS my hand this
Twenty-sixth day of November 2003

J. K. + C.

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Regulation 3.

David Peter Wharton

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

for the invention entitled:

"Drug Delivery Device and Method for Use with an Air Stream"

The invention is described in the following statement:

DRUG DELIVERY DEVICE AND METHOD FOR USE WITH AN AIR STREAM

FIELD OF THE INVENTION

The present invention relates to a device and method for delivery of a drug or drugs to a target organism via the respiratory system. In particular the invention relates to delivery of drugs to a target organism by entraining the drug in a pressurised air stream. More specifically still, the present invention relates to the delivery of a drug or drugs in a pressurised air stream when the recipient is in ambient conditions of increased or decreased atmospheric pressure and reliant on a pressurised respiratory gas supply such as scuba diving under water.

BACKGROUND OF THE INVENTION

The development of self contained underwater breathing apparatus ("scuba") has revolutionised underwater diving for both recreational and professional divers. The simplicity and reliability of modern scuba gear has extended the range and cope of diving activities to a much broader spectrum of society than originally envisaged when the prototype was successfully tested in 1943.

The range of diving activities extends from simple recreational pursuits through to specialised activities such as cave, ice and wreck diving. In warmer waters and particularly in tropical and subtropical areas near coral reefs, there is a great demand for diving tuition, diving expeditions and involvement in general basic diving activities.

In order to be a suitable candidate for undertaking scuba diving, it is necessary to have at least reasonable health with no major relevant disease conditions. Perhaps the commonest obstacle to scuba diving is asthma which is both a pervasive disease in society and an exclusionary condition when considering

diving. The incidence of asthma has been estimated variously at 10% in Australia and New Zealand, 4-7% in the USA and 6-8% in the United Kingdom. Even mild signs of the disease may be sufficient to disqualify participation in scuba diving, the obstructive effect of this condition is very marked. Experienced diving instructors will relate many stories of otherwise seemly perfectly healthy people being excluded from diving classes and the joy of an ocean diving experience, even when that person is asymptomatic. One perceived risk for such a person participating in scuba diving is that a sudden onset of a severe attack at any sort of significant depth could have catastrophic and even fatal consequences. As pressure increases by one atmosphere for every 10 metres of depth, even at a depth of 5 metres, a diver must accommodate a 50% increase in ambient pressure. Respiratory embarrassment, even at this depth, may have significant adverse consequences. One of the unpredictable aspects of asthma is that severity of episodes of dyspnoea is highly variable and also unpredictable.

Aerosol medications are extremely well known for effective therapeutic intervention in an asthma attack when a victim is in normal atmospheric conditions. However, to date, it has not been possible to provide access to such therapeutic agents under water in scuba diving.

It should be noted that while the following disclosure is directed primarily to scuba diving arrangements, it is possible to transfer the same device and method to a wider range of situations for use with pressurised respiratory air supplies. Also the term, drug is used in its widest sense to include agents that are both therapeutic and recreational and agents which may have a mechanical effect on the respiratory tract such as maintaining moisture content or providing a surfactant activity or similar. Further, reference to asthma is exemplary only.

It would be advantageous to provide a means of delivering a drug to a patient in a pressurised air stream under water.

SUMMARY OF THE INVENTION

Throughout this specification, unless the context requires otherwise, the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element or integer or group of elements or integers but not the exclusion of any other element or integer or group of elements or integers.

In one aspect the invention resides in a dosage device for medicated respiration in an underwater environment, the dosage device comprising:

a chamber;

a container locatable in the chamber, the container adapted to store and discharge a therapeutic agent;

a pathway between the chamber and an intake air pathway; and

balance means for substantially equalising the pressure between the chamber and ambient water pressure.

The chamber may form part of a regulator arrangement. Alternatively, the chamber may be in operative proximity to a portion of a regulator arrangement. The chamber is beneficially arranged for cooperation with an air line of an under water breathing apparatus.

The container for storing and discharging a therapeutic agent may be a pressurised canister. The pressurised canister may have a release valve which is pressure activated. The container may deliver a defined dosage of agent. The agent may be one or more of salbutamol (Ventolin®), adrenaline, becisiase (Becotitde®) or any other suitable agent.

The pathway between the chamber and an intake air pathway may arise simply from the chamber being disposed along the intake air pathway. Alternatively, the chamber may communicate with the intake air pathway through at least one bore.

The bore may include valve means operable to open and close the bore. The valve means may be a slide lock. The slide lock may include a locking nut to prevent unintentional activation. The slide lock may include a positioning device such as a pin for indicating when the slide lock is in suitable position to open the bore.

Preferably the device includes two or more pathways between the chamber and an intake air pathway.

The balance means may comprise a compressed air supply source, an intake valve means, an outlet valve means and pressure deformable means for responding to variations between pressure inside the chamber and outside water pressure, wherein the pressure deformable means will release the inlet valve when water pressure significantly exceeds chamber pressure and the outlet valve will release air when the chamber pressure significantly exceeds water pressure.

Preferably the compressed air source is an off-shoot of a primary air line of a breathing apparatus.

In a further aspect, the invention resides in a dosage arrangement for medicated respiration in an underwater environment comprising;

an air supply line;

a second stage regulator chamber connected to the air supply line;

a medication chamber operatively connected to the second stage chamber by at least one air pathway;

a medication canister mounted in the medication chamber and arranged to discharge its contents into the pathway;

a secondary air supply line originating from the air supply line and providing air to the medication chamber;

an intake valve for controlling air delivery to the medicated chamber from

the a secondary air line;

an exhaust valve for discharging air from the medication chamber;

a deformable diaphragm located between ambient water and the medication chamber;

where:

the deformable diaphragm activates a release lever to provide air to the medication chamber when ambient water pressure exceeds the pressure of the medication chamber; and

the exhaust valve releases air from the medication chamber when the air pressure of the chamber exceeds ambient water pressure.

The device may include a pathway control valve for opening and closing the pathway. The control valve may be a slide lock. The slide lock may have an indicator seal for indicating when it has been used. The slide lock may be held in place by a lock nut.

Preferably the device includes two communicating pathways from the medication chamber to the second stage chamber. The two pathways may be aligned with discharge apertures in the medication canister. The discharge apertures may be opened by pressure. Pressure may be applied by an operator through a deformable pad located in a side of the medication chamber. The medication canister may discharge into air flow pathway.

In a further aspect, the invention resides in a pressurised canister for storing a therapeutic agent. The pressurised canister may be formed with a lower amount of agent and at higher pressure than know devices. Further, the canister may have at least two discharge apertures. The apertures may be adapted for simultaneous discharge or may include a mechanism for providing selected discharge through one of the apertures. The canister is preferably adapted for use in the dosage device described above.

BREIF DESCRIPTION OF THE DRAWINGS

Figure 1 is a front view of a dosage device of the present invention.

Figure 2 is a bottom view of the arrangement of Figure 1.

Figure 3 is a side schematic view of an alternative arrangement for dosing a pressurised airstream.

DETAILED DESCRIPTION OF THE DRAWINGS

Scuba diving developed from the technological advance of providing an oxygen mixture under high pressure in a tank with a pressure reducing mechanism for providing the mixture to a person's lungs sufficiently decreased to avoid injury. The principle development related to the production of a regulator for use with either compressed air (78% nitrogen, 21% oxygen) or an oxygen enriched nitrogen oxygen combination called NITROX which includes a range of suitable mixtures. However, the most common range is 64-68% nitrogen and 32-36% oxygen. This gas mixture will be typically held in a metal cylinder which holds approximately 2,200 litres of mixture at approximately 180-230 ATM atmospheres of pressure (ATM).

The regulator is typically provided having a first stage and second stage function. The regulator is adapted to provide air on demand by a user and also reduce the pressure as required.

The first stage of a regulator typically attaches to the cylinder of air and is designed to reduce pressure from the tank at around 204 ATM to an intermediate pressure of around 9.5 ATM.

A length of flexible extendible hose is usually then provided to connect the first

stage to the second stage of the regulator. The second stage is adapted to reduce the mixture at 9.5 ATM to ambient water pressure which is usually in the range of 1-5 ATM depending on depth. The second stage also includes the mechanism for providing air inlet which is activated by inhalation by the diver or in some circumstances has an override for providing air continuously such as in an emergency situation.

The structure of the first stage includes high pressure and intermediate pressure chambers which usually have either a valve diaphragm combination or a piston which are effected by water pressure.

High pressure air is delivered to the first chamber but is subject to controlled release into the second chamber from the action of the diaphragm or piston.

Commonly, the act of breathing will decrease pressure in the secondary chamber leading to an imbalance between the pressure of the air in the chamber and the pressure of surrounding water. A resilient diaphragm may be deformed to activate a push valve thereby clearing a seat and allowing high pressure air from the first chamber into the second chamber. An alternative arrangement uses a somewhat similar function but is based on a hollow piston which moves into and out of register with a cooperating seat with an alternatively closed and clear connecting passageway.

The second stage of the regulator is located adjacent and includes the mouth piece. The second stage has a chamber with a rubber diaphragm in contact with ambient water pressure and an inner valve that is connected to a moveable lever. The second stage also includes an exhaust valve and often has a purge button.

On inhalation the pressure within the second stage drops below the ambient water pressure. As a result, the diaphragm is distorted and comes in contact with the lever which is pivotally mounted and is rotated thereby clearing an inlet line from

the tank. This air is inhaled.

On expiration, the pressure in the second stage of the regulator is increased leading to closure of the air inlet, pressurisation of the diaphragm away from the lever and opening of the exhaust valve.

The above cyclical process is performed sequentially and constantly. The purge button may be used to clear water from the mouth piece and the second stage chamber by introduction of a large quantity of pressured air mix.

Figure 1 shows a front view of a dosage device 10 of the present invention. A primary air line 11 provides a pathway for air 12 or air mixture originating from the pressurised tank on a diver's back. The primary airline 11 terminates in a demand valve 13 which operates in the standard way for delivering pressurised air into the second stage chamber 14 which is shown drawn only in part having partial side walls 15, 16.

A bifurcation results in secondary line 17 which provides compressed feed air to the dosage device 10 of the present invention. It is understood that reference to compressed air includes reference to any appropriate compressed gas or gas mixture including oxygen nitrogen combinations such as NITROX and other gaseous combinations. The dosage device 10 comprises an outer housing 18 which may be formed from any suitable non-flexible material such as metal or polymer. A drug containing canister 19 is positioned in an internal chamber 20 of the dosage device 10.

It is envisaged that the canister 19 will contain a pressurised quantity of therapeutic agent or other form of physiologically or mechanically active substance with a discharge mechanism that is pressure activated. The canister 19 is mounted on two ledges 21 and compressed in place by a suitable packing material such as a tension foil 22. The canister 19 has two outlet apertures 23, 24 which

are urged into close proximity and sealing engagement with the discharge bore. When not in use the apertures are urged against a lock slide 25 which may be formed with a security seal 26, the purpose of which is indicate when the device has been operated thereby indicating to an overseeing diving instructor health professional or other suitable party such as a service or technical agent that the canister may be depleted. In a preferred operation it is envisaged that the canister will be a one use item which may include a number of activations of the device which is disposed of after any single dive in which the device is operated. The lock slide 25 has two through bores 27 which are usually out of alignment with the outlet apertures 23, 24. However, when the device is to be used a rotatable lock screw 28 may be released providing the ability to slide lock slide 25 to a position where the through bores 27 and outlet apertures 23, 24 are in corresponding alignment thereby providing a pathway from the outlet apertures through the through bores and into flow channels 29, 30 directed towards the air stream in the chamber 14 and for inhalation through the mouth piece (not shown). The slide is preferably sealed to prevent ingress of water. O-ring seals may be appropriately located to provide this function. Further the canister apertures 23, 24 may be adapted to sealingly engage the slide rod when the through bores 27 are aligned. O-rings may again be suitable for the purpose.

The present device has an internal chamber 20 which is equalised with ambient water pressure through the demand valve 31 and demand valve lever 32. If the pressure in internal chamber 20 drops below ambient water pressure, the balance diaphragm 33 expands urging the demand valve lever 32 out of its resting position and thereby unseating a valve to allow inlet of air at high pressure into the chamber 20. Should the pressure in the chamber 20 exceed ambient water pressure, air may be discharged through exhaust valve 34. The exhaust valve release pressure of the chamber may be set slightly higher than ambient pressure (ie. increased activation pressure differential required) or the demand lever may be adapted to activate at an increased pressure differential so that the chamber is generally slightly below ambient pressure. The internal chamber 20 is protected

by a chamber seal 35 which abuts a spacer 36 which is in itself in contact with a rubber cover 37. This view also shows an exhaust tube for discharge gas from primary and internal chambers 38.

In operation therefore, a diver will breathe as usual in a scuba diving arrangement. Should the diver find themselves requiring medication of some sort, they will simply unlock the lock slide 25 by rotation of the lock screw 28 and slide the lock slide 25 outwards thereby breaking the seal 26. The lock slide may be fitted with a slide location pin 39 for fixing the lock slide in operating position. Once a pathway is provided between the canister apertures 23, 24 and the flow channels 29, 30 an operator pushes on the rubber cover 37 which leads to depression of the spacer 36, seal 35 and subsequent pressure on the canister 19 leading to activation of the normal discharge aerosol valve as is well known in medihalers such as Ventolin® and Becotitde®. The appropriate number of depressions may be applied to medicate the diver. On completion, the lock slide 25 may be urged back to its original position and the lock screw 28 may be located into locked position.

Figure 2 shows a bottom view of the arrangement of Figure 1 with the exhaust line 38 readily apparent as is the primary exhaust valve 40 which is slightly spaced from medical chamber exhaust having a medical chamber exhaust cover 42. The side wall 43 of the primary regulator chamber is also visible and the primary air line 11 and chamber air line 17 terminating in demand valve 31 and lever 32. The balance diaphragm 33 is visible in close proximity to purge cover 44. The slide 25 and slide lock 28 are provided. Rubber cover 37 is apparent and may have a ridged thumb grip 45. A diaphragm seal is located and outlines medical canister 19 which is shown as visible but may in fact be located behind the outer material.

The present device is suitably adapted for one handed operation by a diver. The hand may grip the chamber wall 43 with a thumb located over thumb operation pad 45 after having released the lock nut 28 and slid lock slide 25 into channel defining location. The canister 19 may be compressed by the thumb of the

appropriate number of times as indicated by the manufacturer or in keeping with the advice of a medical professional.

An alternative arrangement is shown schematically in Figure 3 wherein the drug is delivered to the regulator. In this case a canister 50 is positioned in a bracket 51 formed in the wall 52. A plunger 54 is slideably mounted in a secondary bracket 55 and is actioned by a pivotted lever 56 which is supported on pivot point 57 and rotatably engages the plunger at pivot pin 58.

In turn, the push rod 59 is slideably engaged in clips 60. An activation lever 61 is supported around rotation axis 62 and is resiliently biased to an extended position by spring 63. O-ring seal 64 are used to maintain the integrity of the chamber and prevent any ingress of water. A twist lock 65 is also provided to prevent inadvertent activation of the device.

In use the twist lock 65 is released and the activation lever 61 is depressed one or more times resulting in movement of push rod 59 and subsequent see-sawing action of the pivotted lever 56 causing the plunger 54 to depress and discharge contents of the canister 50 through the discharge aperture 66 and into flow tunnel 67 thereby entraining the medication in the air stream and providing it for respiration by a user.

The advantages of the present invention are readily apparent. The anxiety and real risk of a disease which is treatable via the respiratory tract is to a large degree addressed. A sufferer may, with adequate medical consultation, undertake pursuits which have previously been removed from their experience. The invention may be relatively cheaply constructed but also provides a higher level of reliability and security. The types of drugs, medication or other compounds used is limited only by the availability of materials suitable for the present indications.

Likewise, the present invention may have an operation in applications other than

scuba diving. In a situation where a conscious breathing individual is reliant on a pressurised air stream and requires any form of agent to be administered in that air stream, the dosage device described above may provide the opportunity for sensible self medication.

Throughout the specification the aim has been to describe the preferred embodiments of the invention without limiting the invention to any one embodiment or specific collection of features. Those of skill in the art will therefore appreciate that, in light of the instant disclosure, various modifications and changes can be made in the particular embodiments exemplified without departing from the scope of the present invention. All such modifications and changes are intended to be included within the scope of the disclosure.

DATED this 15th day of November 2002

David Peter Wharton

by DAVIES COLLISON CAVE

Patent Attorneys for the Applicants

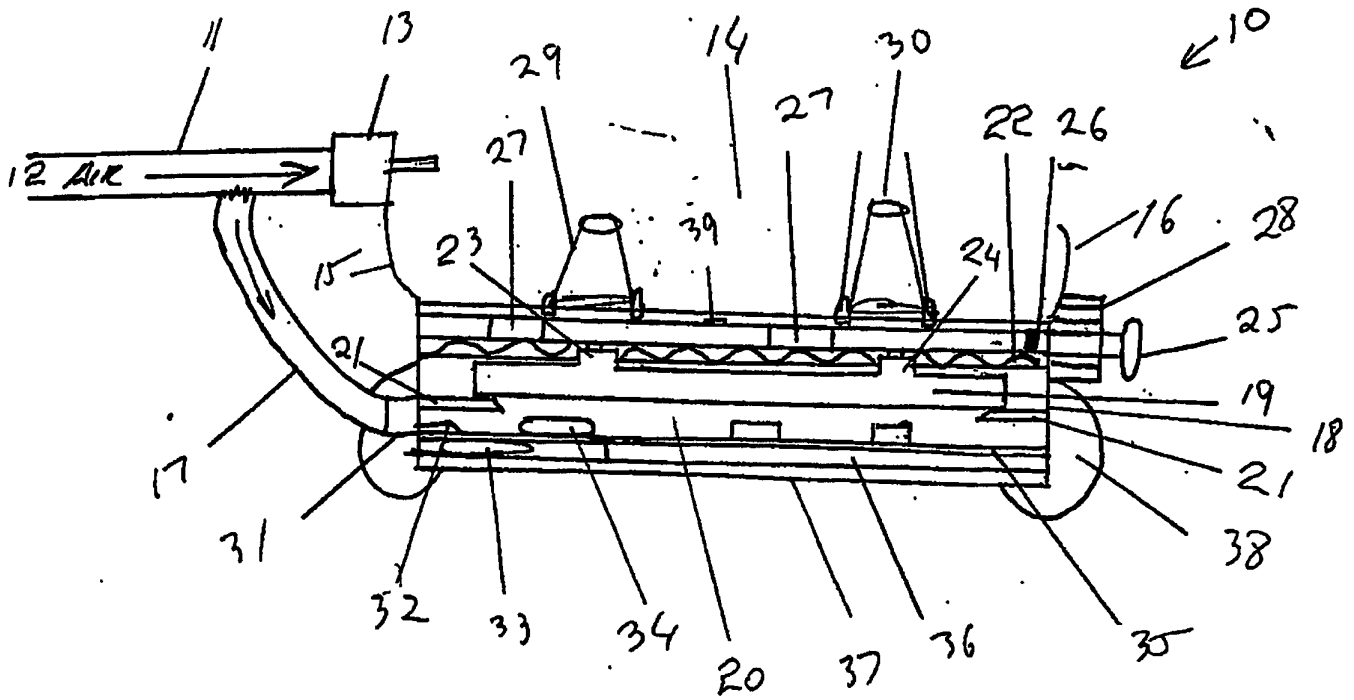
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FIGURE 1

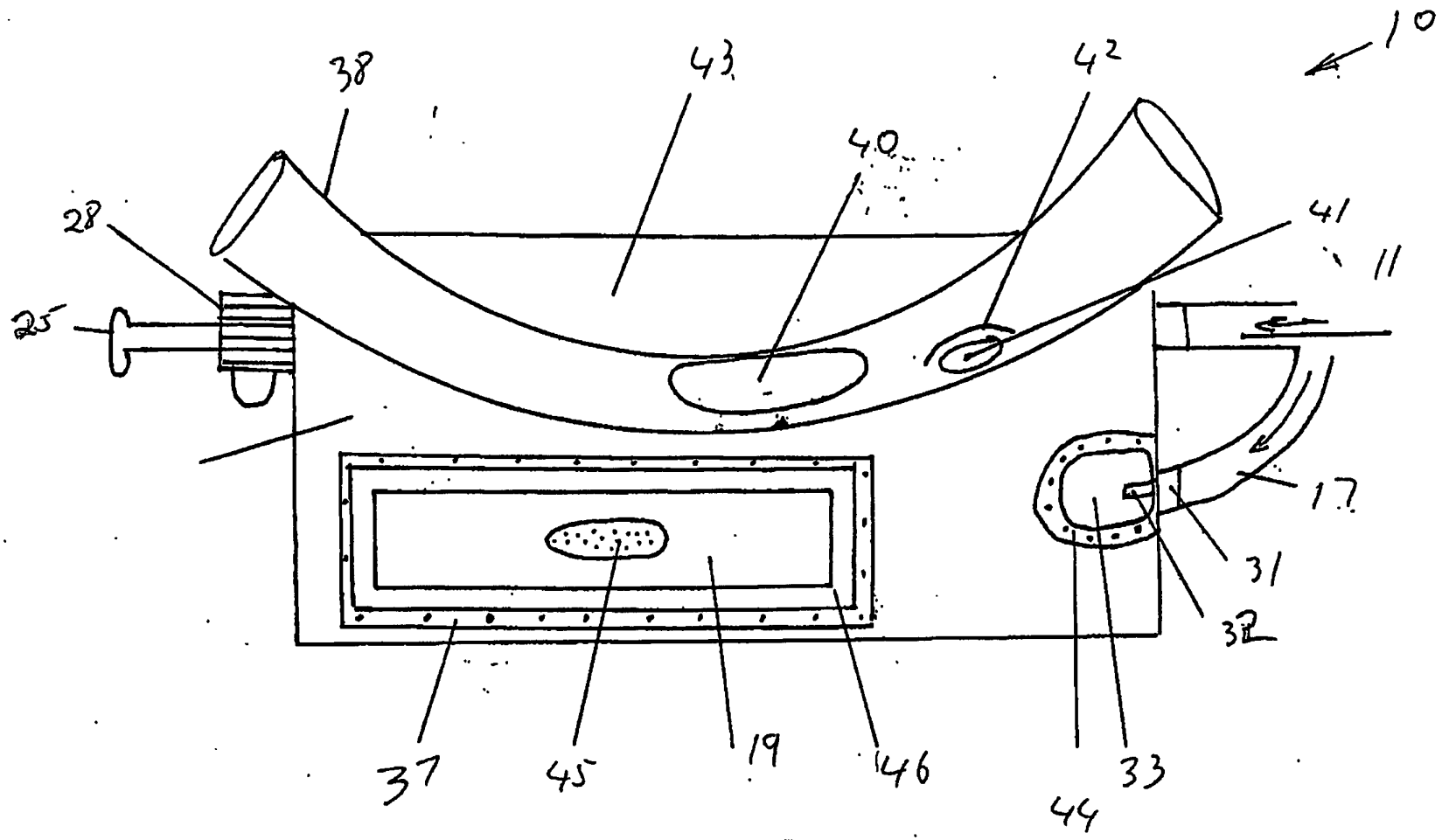

FIGURE 2

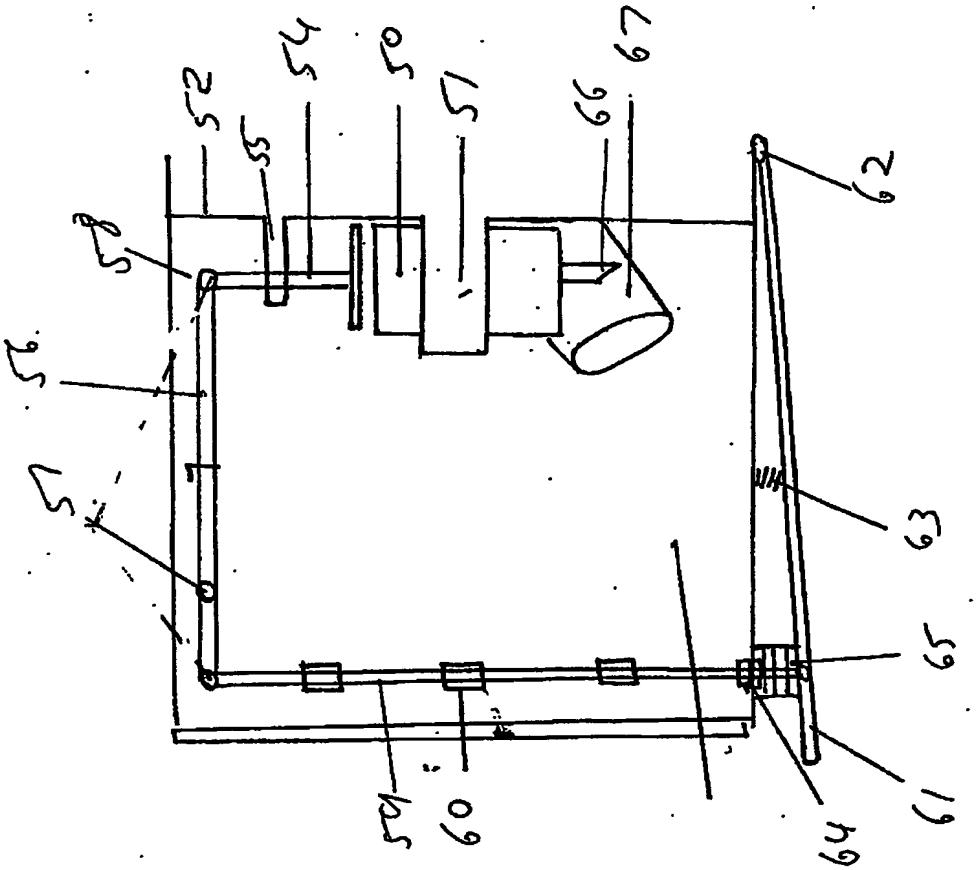

FIGURE 3